



UNITED STATES DEPARTMENT OF COMMERCE  
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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
08/486,066	06/07/95	ENGELHARDT	ENZ (D5) (C2)

HM31/0318

ENZO DIAGNOSTICS, INC.  
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EXAMINER

MARSCHEL, A

ART UNIT PAPER NUMBER

1634

36

DATE MAILED: 03/18/98

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

# Office Action Summary

Application No.  
**08/486,066**

Applicant(s)  
**Engelhardt et al.**

Examiner  
**Marschel, Ardin**

Group Art Unit  
**1634**



☒ Responsive to communication(s) filed on Dec 29, 1997

☒ This action is **FINAL**.

☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

A shortened statutory period for response to this action is set to expire 3 month(s), or thirty days, whichever is longer, from the mailing date of this communication. Failure to respond within the period for response will cause the application to become abandoned. (35 U.S.C. § 133). Extensions of time may be obtained under the provisions of 37 CFR 1.136(a).

## Disposition of Claims

☒ Claim(s) 238-297 and 299-338 is/are pending in the application.

~~Revised~~ Claim(s) 1-237 and 298 have been canceled. ~~is/are withdrawn from consideration~~

☐ Claim(s) \_\_\_\_\_ is/are allowed.

☒ Claim(s) 238-297 and 299-338 is/are rejected.

☐ Claim(s) \_\_\_\_\_ is/are objected to.

☐ Claims \_\_\_\_\_ are subject to restriction or election requirement.

## Application Papers

☐ See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.

☐ The drawing(s) filed on \_\_\_\_\_ is/are objected to by the Examiner.

☐ The proposed drawing correction, filed on \_\_\_\_\_ is ☐ approved ☐ disapproved.

☐ The specification is objected to by the Examiner.

☐ The oath or declaration is objected to by the Examiner.

## Priority under 35 U.S.C. § 119

☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).

☐ All ☐ Some\* ☐ None of the CERTIFIED copies of the priority documents have been received.

☐ received in Application No. (Series Code/Serial Number) \_\_\_\_\_.

☐ received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

\*Certified copies not received: \_\_\_\_\_.

☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

## Attachment(s)

☐ Notice of References Cited, PTO-892

☐ Information Disclosure Statement(s), PTO-1449, Paper No(s). \_\_\_\_\_

☐ Interview Summary, PTO-413

☐ Notice of Draftsperson's Patent Drawing Review, PTO-948

☐ Notice of Informal Patent Application, PTO-152

--- SEE OFFICE ACTION ON THE FOLLOWING PAGES ---

The art unit designated for this application has changed. Applicant(s) are hereby informed that future correspondence should be directed to Art Unit 1634.

Applicants confusingly asked to have the finality of the office action, mailed 6/23/97 to be withdrawn pursuant to 37 CFR § 1.129(a). This has not been entered because the office action, mailed 6/23/97, was not a final action thus making this election moot.

Applicants' arguments, filed 12/29/97, have been fully considered but they are not deemed to be persuasive. Rejections and/or objections not reiterated from previous office actions are hereby withdrawn. The following rejections and/or objections are either newly applied or reiterated. They constitute the complete set presently being applied to the instant application.

Claims 238, 240-272, 274-297, 299-308, and 310-338 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for claims limited to covalent attachment of the Sig or PM moieties to the sugar (SM) via the hydroxyls at the 2', 3', or 5' positions of ribose or deoxyribose sugars, it does not reasonably provide enablement for claims that broadly lack limitation to said 2', 3', or 5' sugar ring attachment points. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to the invention commensurate in scope with these claims. It is noted that applicants have amended the independent claims to require either a ribose or deoxyribose

sugar. This amendment, however, lacks the limitation to require attachment at the 2', 3', or 5' positions as also being required for instant enablement. Therefore this rejection is maintained for those claims that do not contain the limitations to said sugar ring positions. This rejection is maintained and modified as described above from the previous office action, mailed 6/23/97. Applicants argue that the claims have been amended corresponding to this rejection. It is noted as above that the sugar ring position limitations, however, have not been amended into the above rejected claims.

The following is a quotation of the appropriate paragraphs of 35 U.S.C. § 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless --

(a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 238-240, 242, 243, 245, 246, 249, 262, 264, 269, 270, 272-274, 276, 277, 279, 283, 296, 304, 306-310, 312, 313, 315, 319, 329-331, 336, and 338 are rejected under 35 U.S.C. § 102(a) as being clearly anticipated by Caruthers (1982).

It is noted that the DNA volume 1(2) that discloses Caruthers (1982) is date stamped as being received at the U.S. PTO on March 7, 1982. Caruthers discloses deoxyribose

nucleotides that meet the instant claims as having detectable Sig moieties such as dimethoxy-trityl or acetyl moieties as well as a phosphate moiety attached to SM in the form of a phosphine moiety.

Claims 238-243, 245, 246, 249, 255, 256, 262, 264, 265-277, 279, 280, 283, 289, 290, 296, 299, 301-313, 315, 316, 319, 325, 326, 329-333, and 336-338 are rejected under 35 U.S.C. § 102(b) as being clearly anticipated by Kourilsky et al. (GB 2,019,408).

Kourilsky et al. discloses the preparation of nucleotide, deoxynucleotides, and oligomers thereof with biotin labels as well as mercury and SH groups on page 2, lines 34-52. The polynucleotides attached to a particular nucleotide via the sugar-phosphodiester backbone meets the requirements of the instantly claimed and linked Sig moieties attached to a nucleotide with a phosphate moiety also attached.

No claim is allowed.

Applicants' amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicants are reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for response to this final action is set to expire THREE MONTHS from the date of this action. In the event a first response is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event will the statutory

period for response expire later than SIX MONTHS from the date of this final action.

Since the fee set forth in 37 CFR 1.17(r) for a first submission subsequent to a final rejection has been previously paid, applicant, under 37 CFR 1.129(a), is entitled to have a second submission entered and considered on the merits if, prior to abandonment, the second submission and the fee set forth in 37 CFR 1.17(r) are filed prior to the filing of an appeal brief under 37 CFR 1.192. Upon the timely filing of a second submission and the appropriate fee for a large entity under 37 CFR 1.17(r), the finality of the previous Office action will be withdrawn. If a notice of appeal and the appeal fee set forth in 37 CFR 1.17(e) were filed prior to or with the payment of the fee set forth in 37 CFR 1.17(r), the payment of the fee set forth in 37 CFR 1.17(r) by applicant will be construed as a request to dismiss the appeal and to continue prosecution under 37 CFR 1.129(a). In view of 35 U.S.C. 132, no amendment considered as a result of payment of the fee set forth in 37 CFR 1.17(r) may introduce new matter into the disclosure of the application.

Papers related to this application may be submitted to Group 1600 by facsimile transmission. Papers should be faxed to Group 1600 via the PTO Fax Center located in Crystal Mall 1. The faxing of such papers must conform with the notices published in the Official Gazette, 1096 OG 30 (November 15, 1988), 1156 OG 61 (November 16, 1993), and 1157 OG 94 (December 28, 1993) (See 37 CFR § 1.6(d)). The CM1 Fax Center number is (703) 308-4242.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Ardin Marschel, Ph.D., whose telephone number is (703) 308-3894. The examiner can normally be reached on Monday-Friday from 8 A.M. to 4 P.M.

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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, W. Gary Jones, can be reached on (703) 308-1152.

Any inquiry of a general nature or relating to the status of this application should be directed to the Chemical Matrix receptionist whose telephone number is (703) 308-0196.

March 13, 1998

*Ardin H. Marschel*  
ARDIN H. MARSCHEL  
PRIMARY EXAMINER